

# EXHIBIT 5



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

June 27, 2007

Brian Robert Lowry  
Monsanto Company  
800 North Lindbergh Blvd  
St. Louis, Missouri 63167

Dear Mr. Lowry:

This letter responds to your February 22, 2007, letter concerning milk labeling practices with regard to Recombinant Bovine Somatotropin (rBST). You ask FDA to issue additional warning letters and to revise existing guidance on the issue.

In support of your request, you cite a number of examples that you believe are misleading. We note, however, that the majority of your examples involve milk advertising practices, which the Federal Trade Commission, not FDA, has the authority to regulate. Such practices, therefore, do not warrant our revising our existing guidance.

With regard to those claims that actually appear on milk labels, FDA has taken several actions regarding milk labeling practices with regard to rBST. As you are aware, in 1994 the agency issued a guidance concerning the voluntary labeling of milk and milk products from cows that have not been treated with rBST. Subsequently, FDA issued warning letters when milk labels contained false statements that milk from cows not treated with rBST contained no hormones.

FDA will continue to enforce the misbranding provisions of the Federal Food, Drug, and Cosmetic Act. In particular, we will issue warning letters when milk labeling regarding rBST is false or misleading. With respect to your request that we revise the 1994 guidance, you candidly acknowledge that doing so would "require substantial investment of time and agency resources." In light of FDA's many responsibilities, we do not intend, at present, to invest the substantial amount of time necessary to revise the guidance.

Sincerely,

A handwritten signature in black ink, appearing to read "Sheldon T. Bradshaw", is written over the word "Sincerely,".

Sheldon T. Bradshaw  
Chief Counsel  
Food and Drug Administration

cc: Andrew von Eschenbach, M.D.  
Stephen Sundloff, D.V.M., Ph.D.  
Robert Brackett, Ph.D.